

REMARKS

Claim Rejections - 35 U.S.C. §112 First Paragraph

Claims 7-11 are elected and claims 12 and 13 have been cancelled without prejudice in response to the restriction of claims by the Examiner.

The Examiner has rejected claims 7-11 under 35 U.S.C. §112, first paragraph on the basis that any glycosidase derived from *Xanthomonas* is claimed for use in modifying any carbohydrate. The Examiner has asserted lack of description and enablement for any glycosidase absent a function/activity relationship with the described glycosidases. Furthermore, the Examiner asserts lack of representative species other than *Xanthomonas manihotis*.

In response to the Examiner's rejection, Claim 7 has been amended and now recites in place of any glycosidase, specific glycosidases from *Xanthomonas*. These specific glycosidases are fucosidase, mannosidase, xylosidase, glucosidase, galactosidase, N-acetylglucosaminidase or hexosaminidase. Support for these glycosidases may be found for example, in Table 5 and in the Application as follows:

fucosidase; on pages 30, 31 and 42

mannosidase; on pages 30,31 and 47

xylosidase; on page 31, 78

glucosidase; page 48
galactosidase; page 30, 31 and 45
N-acetylglucosaminidase; page 43
hexosaminidase; Table 7

Multiple glycosidases from multiple strains of *Xanthomonas* are summarized in Table 4 and shown in Figure 2. Table 4 lists the glycosidases identified from a glycosidase screen using *Xanthomonas holcicola*, *Xanthomonas badrii*, *Xanthomonas manihotis*, *Xanthomonas oryzae*, *Xanthomonas cyanopsidis*, and *Xanthomonas campestris*. A detailed description of how the screen was conducted is provided on pages 20- 28, Example 2 and Figure 2 and includes ATCC number designations for the strains used.

Methods for screening for novel glycosidases for use in modifying carbohydrates is provided on pages 28- 32 and Example 7 of the Application. Methods for identifying novel glycosidases obtained from the screening methodology are described on page 28 and 29. In particular, page 29 describes how the substrate specificity of novel glycosidases can be determined. Use of specific glycosidases obtained using screening, purifying and characterizing methodologies described in detail herein can be used to modify the carbohydrates as described on page 32 of the Application.

The Examiner has stated that only glycosidases from *Xanthomonas manihotis* have been described. Applicants

respectfully disagree (see above, including Table 4 and Figure 2) and Examples 3, 9 and 11. Example 3 describes how to purify glycosidases from *Xanthomonas manhotis*, Example 9 describes purifying glycosidases from *Xanthomonas holcicola*, and Example 11 describes purification of glycosidases from *Xanthomonas oryzae*.

The Examiner has asserted that the specification is only enabled for modifying a carbohydrate using a fucosidase or galactosidase from *Xanthomonas manhotis*. Applicants respectfully disagree. Modification of a carbohydrate using a glycosidase occurs when a specific terminal monosaccharide is removed. Removal of terminal monosaccharides has been determined for example, using chromogenic monosaccharide derivatives such as p-nitrophenyl glycopyranoside (page 21 of the application) or fluorescently labeled oligosaccharides such as AMC substrates (page 22 of the specification) by TLC (pages 25-26 of the Application). Examples 3 and 4 describe modifying a carbohydrate with any of a fucosidases, an N-acetylglucosaminidase, mannosidases, galactosidases, a glucosidase and a xylosidase from *Xanthomonas manhotis*. Example 9 and 11 describes a plurality of different glycosidases from *Xanthomonas holcicola* and *Xanthomonas oryzae* including xylosidase and mannosidase.

Taken as a whole, Applicants assert that criteria cited by the Examiner from *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)] have been met and sufficient of direction or guidance is

presented together with working example to enable a skilled artisan to practice the modifying carbohydrates using the specified glycosidases from *Xanthomonas* defined by amended claims 7-11 without undue experimentation.

Claim Rejections - 35 U.S.C. §112, 2nd Paragraph

Claims 7 and 9-11 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In claim 7, the phrase "one glycosidase derived from *Xanthomonas*" renders the claim vague and indefinite because the specific glycosidase claimed is not known and not recited. This has been amended and is believed to be allowable. Claims 9-11 which depend from claim 7 should also now be allowable.

In claim 9, the phrase "biological properties which differ from the glycosidase derived from *Xanthomonas*" renders the claim vague and indefinite because the meaning of the phrase is not known and it is not known what specific biological properties of the modified carbohydrate are to be different from the "glycosidase derived from *Xanthomonas*". Claim 9 has been amended to more distinctly point out the invention and is now believed to be allowable. Claims 10 and 11 which depend from claim 9 and are believed to be allowable.

In claim 10, the phrase "altering the immunogenic properties of a glycoprotein" renders the claim vague and indefinite because the specific glycoprotein and its immunogenic properties which are to be altered are not known and not recited in the claim. It is asserted that a skilled artisan would know that modification of a carbohydrate by cleaving terminal monosaccharides using glycosidases modifies the immunogenic properties of the carbohydrate where the immunogenic properties reside in the precise recognition of epitopes on a molecule where epitopes are characterized by molecular composition and configuration.

For the reasons set forth above, Applicants respectfully submit that the rejections set forth in the Final Rejection mailed March 11, 2003 have been overcome and that this case is in condition for immediate allowance. Early and favorable consideration leading to prompt issuance of this Application is earnestly solicited.

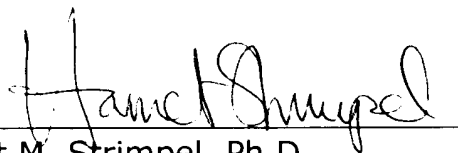
Wong-Madden, et al.
U.S.S.N.: 10/003,136
Filed: November 15, 2001
Page 9

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned Attorney would appreciate the opportunity to do so. Thus, the Examiner is hereby authorized to call the undersigned, collect, at the number shown below.

Respectfully submitted,

NEW ENGLAND BIOLABS, INC.

Date: 9/5/03



Harriet M. Strimpel, Ph.D.
(Reg. No. 37008)
Patent Counsel
32 Tozer Road
Beverly, MA 01915
(978) 927-5054 X: 373